

REMARKS/ARGUMENTS

The present Amendment and Response comprises Applicants' reply to the Examiner's non-final Office Action mailed on December 30, 2008. Claim 2 was previously cancelled. Claims 3 and 4 are amended. Claims 7 and 10 have been cancelled as being redundant of Claims 5 and 6, respectively. Accordingly, Claims 1, 3-6, 8-9 and 11-12 are now pending in view of the above amendments.

Applicants believe that no new matter has been added with regard to the claim amendments provided herein. Applicants do not waive or disclaim any claims or subject matter with the claim amendments made herein, and the Applicants expressly reserve the right to prosecute the original claims or any unclaimed subject matter in one or more future filed continuing applications.

Reconsideration of the application is respectfully requested in view of the above amendments to the claims and the following remarks. Please note that the following remarks are not intended to be an exhaustive enumeration of the distinctions between any cited references and the claimed invention. Rather, the distinctions identified and discussed below are presented solely by way of example to illustrate some of the differences between the claimed invention and the cited references. In addition, the Applicants request that the Examiner carefully review any references discussed below to ensure that Applicants' understanding and discussion of the references, if any, is consistent with the Examiner's understanding. Also, Applicants' arguments related to each cited reference are not an admission that the cited references are, in fact, prior art.

I. Claim Objections

The Examiner objected to Claim 3 for informality, specifically, the term “Claim 1” was referred to as “Claim I.” In response, Applicants have amended Claim 3 to correct this error, and request that the Examiner remove this objection.

II. Rejection Under 35 U.S.C. § 112, Second Paragraph

The Examiner rejected Claims 3 and 4 under 35 U.S.C. § 112, Second Paragraph for indefiniteness on the grounds that there is insufficient antecedent basis for the term “hot water.” Applicants have amended Claims 3 and 4, to correct this rejection and request that the Examiner remove this rejection.

III. PRIOR ART REJECTIONS

A. Rejection Under 35 U.S.C. § 102(b)

The Examiner rejected Claims 1, 3-5, and 7-9, under 35 U.S.C. § 102(b) as being anticipated by Sohn et al. (203, Phytomedicine, 10, 165-167). Claim 7 has been cancelled as being redundant of Claim 5, leaving Claims 1, 3-5 and 8-9 as pending relevant to this rejection.

In the Office Action, the Examiner stated that Sohn et al. teaches seeds of *N. nucifera* extracted with ethanol under reflux for three hours and filtrate was evaporated in vacuo; *N. nucifera* is also known as *Nelumbinis semen* or lotus seed (see <http://www.tcmbasics.com/materiamedica/semmennelumbinis.htm>); the process of refluxing requires heating a solution from aqueous to gas phase and ethanol is dissolved in water; boiling of water in one atmospheric pressure requires the temperature to be 100 degree Celsius. The Examiner stated that therefore, water is inherently taught by the reference to be heated to 100 degree Celsius.

It is well recognized that claims are anticipated if, and only if, each and every element, as set forth in the claim is found in a single prior art reference. Vertegaal Bros. v. Union Oil Co. of Calif., 814 F.2d 628, 631 (Fed. Cir. 1987). Furthermore, "[t]he identical invention must be shown as a complete detail as contained in the . . . claim." Richardson v. Suzuki Motor Co., 868 F.2d 1226, 1236 (Fed. Cir. 1989). See MPEP § 2131. To constitute anticipation, all material elements of the claim must be found in one prior art source. In re Marshall, 198 U.S.P.Q. 344 (C.C.P.A. 1978). Additionally, the elements of the reference must be arranged as required by the claim. In re Bond, 15 U.S.P.Q. 2d 1566 (Fed. Cir. 1999). Applicant respectfully submits that the cited reference does not teach all the materials elements and do not arrange the elements as required by the rejected claim language.

Applicants assert that Claims 1, 3-5 and 8-9 cannot be anticipated by Sohn. First, Sohn does not disclose the use of Nelumbinis Semen extract as a composition for the treatment of depression. Rather, Sohn only discloses the use of a specific extract having antioxidant and hepatoprotective effects. Functional language in the claims, such as the language in the present claims reading "having antidepressive activity," or "for treating depression" must be given patentable weight in evaluating the novelty of such claims. In re Land, 368 F.2d 886, 151 U.S.P.Q. 621 (C.C.P.A. 1966); In re Mills, 916 F.2d 680, 16 U.S.P.Q. 2d 1430 (1990).

Second, Sohn discloses an ethanol extraction for 3 hours, not a hot water extraction for 1-3 hours as required by the claims of the present application. In order for the extraction in Sohn to produce an extract with antioxidative and hepatoprotective effects, the extraction in Sohn requires heating a solution from aqueous to gas phase wherein the solution comprises ethanol dissolved in water. Merely because water is used to dissolve the ethanol for the extraction in Sohn, this does not change the type or nature of the extraction being performed from an ethanol

extraction to a hot water extraction. More particularly, the extraction described in Sohn is an alcohol solution extraction, namely an ethanol solution extraction. And, even though it uses water in the ethanol solution, it does not anticipate or even make obvious the hot water extraction that is specifically disclosed in the present application. See ¶ [71] describing the hot water extraction of the present invention. The hot water extraction method of the present claims does not use any ethanol, and in fact, as described in more detail below, use of an ethanol or ethanol solution extract produces a different extract composition than the hot water extraction process disclosed in the present application.

Specifically, Sohn itself clearly states that an ethanol, not a hot water, extraction is being used, and solely for the purposes of arriving at an extract with antioxidative and hepatoprotective effects:

Ethanol extracts from *Nelumbo nucifera* (ENN) seeds were studied for possible antioxidative and hepatoprotective effects. Antioxidative effects were measured spectrophotometrically by reduction of 2,2'-Diphenyl-1-picrylhydrazyl (DPPH) radicals. Hepatoprotective effects were tested using carbon tetrachloride (CCl₄) and aflatoxin B1 (AFB1)-induced hepatocyte toxicity models. ENN showed potent free radical scavenging effects with a median inhibition concentration of 6.49 g/ml. Treatment of hepatocytes with ENN inhibited both the production of serum enzymes and cytotoxicity by CCl₄. The genotoxic and cytotoxic effects of AFB1 were also inhibited by ENN in dose-dependent manners. These hepatoprotective effects of ENN against CCl₄ and AFB1 might result from its potent antioxidative properties. (emphasis added)

Additionally, the type or nature of the extraction used to produce extracts from *Nelumbo nucifera* results in different extraction products. Thus, the extract produced from an ethanol extraction would necessarily be a different extract than that produced from a hot water extraction. Compare Exhibits 1A and 1B attached hereto. Exhibit 1A shows a chromatogram and its three-dimensional plot of an ethanol extract from *Nelumbinis semen*; whereas, Exhibit 1B shows a chromatogram and its three-dimensional plot of a hot water extract from *Nelumbinis*

semen. A comparison of the chromatograms in Exhibits 1A and 1B clearly show that the different extractions result in two different extraction products (specifically, note the absence of Peaks 1, 2 and 3 in the hot water extraction product chromatogram).

Thus, Sohn only anticipates the specific *Nelumbo nucifera* extract resulting from ethanol extraction that has antioxidant properties and assists in protecting liver cells from damage – not the extract that would be derived from hot water extraction for use in treating depression. Thus, the major distinctions between the extraction method and purpose or use of the resulting extract in Sohn and those in the present invention are more than sufficient to overcome Examiner's rejection based on 102(b). Therefore, Applicant respectfully requests that Examiner withdraw her 102(b) rejection based on Sohn.

The Examiner also rejected Claims 1, 3-5, and 7-9, under 35 U.S.C. § 102(b) as being anticipated by Akiyama et al. (JP Patent No. 63066126 A). Claim 7 has been cancelled as being redundant of Claim 5, leaving Claims 1, 3-5 and 8-9 pending as relevant to this rejection.

In the Office Action, the Examiner stated that Akiyama et al. teaches a drug from lotus seed embryo bud extracted by water, then concentrated the extract solution by refluxing for 5 hours; Lotus seed is also known as *Nelumbinis semen* (see <http://www.tcmbasics.com/materiamedica/semmennelumbinis.htm>); the process of refluxing requires heating a solution from aqueous to gas phase, which requires boiling water. Boiling of water in one atmospheric pressure requires the temperature to be 100 degree Celsius. Therefore, water is inherently taught by the reference to be heated to 100 degree Celsius.

Applicants assert that Claims 1, 3-5 and 8-9 cannot be anticipated by Akiyama et al. Specifically, Akiyama et al. teaches an extract from lotus seed embryo bud. Lotus seed embryo bud is not the same as lotus seed or *Nelumbinis semen*. Lotus seed as used for extraction in the

present invention and other applications refers to the seed after the removal of the seed's embryonic bud. The embryonic bud is the core of the lotus seed which resides inside the seed, between the two seed leaves. Compare Exhibit 2A and Exhibit 2B. Exhibit 1B is a picture of the Nelumbinis semen as it appears prior to extraction, with the embryonic bud already removed. Exhibit 2B is a picture of lotus seed embryonic bud.

The lotus seed, as used in the extraction in the present invention, and is commonly referred to for other lotus seed extractions for medicinal use, refers specifically to the debudded seed. See Lotus Seed (March 2002, <http://www.itmonline.org/arts/lotus.htm>)(Inside the seed is a green embryo that is quite bitter and usually removed before using the seed leaves). The debudded seed then used for extraction usually appears as half seeds (the two seed leaves having been separated to remove the embryonic bud). Thus, the lotus seed as it appears in Exhibit 1B is the Nelumbinis seed used in the extraction of the present invention; whereas the embryonic bud as shown in Exhibit 2B is the base product from which Akiyama extracts its pharmaceutical composition with hypotensive properties. Accordingly, the embryonic bud and its resulting extracts have different properties and uses than the seed itself. The present invention does not use or perform an extraction on the embryonic bud.

Additionally, Akiyama et al. does not disclose the use of Nelumbinis Semen extract as a composition for the treatment of depression. Rather, Akiyama only discloses the use of a specific extract having hypotensive properties. Functional language in the claims, such as the language in the present claims reading "having antidepressive activity," or "for treating depression" must be given patentable weight in evaluating the novelty of such claims. *In re Land*, 368 F.2d 886, 151 U.S.P.Q. 621 (C.C.P.A. 1966); *In re Mills*, 916 F.2d 680, 16 U.S.P.Q. 2d 1430 (1990).

Thus, Akiyama only anticipates the specific embryonic bud extract that has hypotensive properties – not Nelumbinis seed extract that is derived from hot water extraction for use in treating depression. Thus, the major distinctions between the actual base product being used for the extraction (Nelumbinis seed versus embryonic bud), the resulting extract, and purpose or use of the resulting extract (in Akiyama for lowering blood pressure and in the present invention for use in treating depression) are more than sufficient to overcome Examiner’s rejection based on 102(b). Therefore, Applicant respectfully requests that Examiner withdraw her 102(b) rejection based on Akiyama.

The Examiner rejected Claims 5-7 and 10, under 35 U.S.C. § 102(b) as being anticipated by Lotus Seed (March 2002, <http://www.itmonline.org/arts/lotus.htm>). Applicant has cancelled Claims 7 and 10, as being redundant of Claims 5 and 6, respectively, leaving Claims 5 and 6 pending as relevant to this rejection.

In the Office Action, the Examiner stated that Lotus Seed teaches lotus seed boiled in water and simmered for 1.25 to 1.5 hours or until the beans are tender; Lotus seeds can be used for food and medicine; Lotus seed is also known as Nelumbinis Semen (see <http://www.tcmbasics.com/materiamedica/semmennelumbinis.htm>); boiling of water in one atmospheric pressure requires the temperature to be 100 degree Celsius.

Applicants assert that pending Claims 5 and 6 are not anticipated by Lotus Seed: Food and Medicine (hereinafter referred to as “Lotus Seed”). First, Lotus Seed discloses the boiling of lotus seed only when used in a food recipe such as red bean and lotus seed soup or cream lotus seed soup – not for producing a pharmaceutical composition for use in treating depression, as claimed in Claim 5. Second, the Examiner appears to assert that the seeds are boiled for 1.25 to

1.5 hours, thus anticipating the presently claimed method of hot water extraction at a temperature of 80-100 degrees Celsius for 1-3 hours.

However, the Lotus Seed disclosure cited to by the Examiner in preparation of red bean and lotus seed soup actually states that one “Bring [water, red beans, lotus seeds and tangerine skin] to a boil over high heat, reduce heat and simmer” for 1.25 to 1.5 hours or until beans become tender. Because the heat is reduced immediately after the water boils, the lotus seeds are not subjected to boiling for the entire 1.25 to 1.5 hours, but only a fraction of that time. Further, the simmering time of the water and lotus seeds is actually dependent on the time it takes for the red beans to become tender – not a specific range of time between one and three hours. Additionally, there is no disclosure that the actual temperature of the water when one simmers the soup is between 80 and 100 degrees Celsius. Moreover, there is no disclosure that preparing the soup as instructed actually results in extracting any composition from the lotus seed, much less a resulting soup or resulting extract in the soup that is useful for treating depression or having anti-depressive activity.

In fact, no-where in the entire Lotus Seed disclosure is there a reference to use of lotus seed or Nelumbinis semen for treating depression or having anti-depressive activity. Again here, functional language in the claims, such as the language in the present claims reading “having antidepressive activity,” or “for treating depression” must be given patentable weight in evaluating the novelty of such claims. *In re Land*, 368 F.2d 886, 151 U.S.P.Q. 621 (C.C.P.A. 1966); *In re Mills*, 916 F.2d 680, 16 U.S.P.Q. 2d 1430 (1990).

Applicant agrees with Examiner that Lotus Seed does generally disclose medicinal uses. Notably Lotus Seed provides a laundry list of potential medicinal uses for lotus seed, lotus embryos, lotus leaves and lotus stamens. However, no-where in this laundry list of potential

medicinal uses is there mention of treatment for depression or antidepressive activity. The absence of treatment for depression or antidepressive activity as a use for lotus seed extract in Lotus Seed, among a fairly comprehensive laundry list of known medicinal uses for various forms of lotus seed, strongly points to the novelty of Applicants' invention as disclosed in the present application.

Here then neither the method for making the red bean and lotus seed soup nor the disclosure of a variety of medicinal uses (none of which are a treatment for depression) in Lotus Seed anticipate Claims 5 and 6. The failures of Lotus Seed both to disclose the comprising extract or use of pharmaceutical composition or health food as claimed in Claims 5 and 6, are sufficient to overcome Examiner's rejection based on 102(b). Therefore, Applicants respectfully request that Examiner withdraw her 102(b) rejection based on Lotus Seed.

B. Rejection Under 35 U.S.C. § 102(b) or 103

The Examiner rejected Claims 1 and 3-12 under 35 U.S.C. § 102(b) as anticipated by or, in the alternative, under 35 U.S.C. § 103 as being unpatentable over Bae et al. (KR 1020030079104 A). Claims 7 and 10 have been cancelled, leaving Claims 1, 3-6, 8-9 and 11-12 pending in the application. The Examiner stated Bae et al. teaches a pharmaceutical composition and health food of an extract of *Nelumbinis semen* for the treatment of depression. The Examiner stated that the cited reference teaches a composition of 1-100% ethanol or methanol, filtering and concentrating the concentrate, as the active ingredient therein which appears to be identical to (and thus anticipate) the presently claimed extract *Nelumbinis Semen* composition since the prepared ingredient has similar aqueous extraction, concentration steps, and demonstrate the same/similar activity with respect to treating depression. The Examiner

believes, the instantly claimed red vine leaf extract composition appears to be anticipated by the Bae reference.

The Examiner stated that, in the alternative, even if the claimed Nelumbinis Semen composition is not identical to the referenced Nelumbinis Semen extract composition with regard to some unidentified characteristics, the differences between that which is disclosed and that which is claimed are considered to be so slight that the referenced Nelumbinis Semen composition is likely to inherently possess the same characteristics of the claimed Nelumbinis Semen composition particularly in view of the similar characteristics which they have been shown to share. The Examiner believes the claimed Nelumbinis Semen composition would have been obvious to those of ordinary skill in the art within the meaning of USC 103, and, if not anticipated, the result-effective adjustment of particular conventional working conditions (e.g., for use as pharmaceutical and health food to treat depression) is deemed merely a matter of judicious selection and routine optimization which is well within the purview of the skilled artisan. The Examiner noted that an invention's patentability of a product does not depend upon its method of product.

The U.S. Supreme Court, in KSR Int'l. Co. v. Teleflex Inc., 82 USPQ 2d 1385, 1391 (2007), reiterated the standard for determining obviousness under 35 U.S.C. § 103 as being the factual inquiries set forth in Graham v. John Deere Co. of Kansas City, 383 U.S. 1 (1966). In Graham, the Court stated that obviousness is determined by first determining the scope and content of the prior art, then ascertaining the differences between the invention, as claimed, and the prior art, and then resolving the level of ordinary skill in the prior art. Against this background, the obviousness or non-obviousness of the claimed subject matter is determined. Secondary considerations may also be utilized in this analysis to give light to the circumstances

surrounding the origin of the subject matter sought to be patented. KSR Int'l Co., 82 USPQ 2d at 1391. When making any obviousness rejection, the Examiner must first acquire a thorough understanding of the claimed invention by reading the specification and claims to understand what the Applicant is claiming as his invention. MPEP § 904.

To establish a *prima facie* case of obviousness under 35 U.S.C. §103(a), the Examiner must clearly articulate the reason(s) why the claimed invention would have been obvious (i.e., the analysis supporting the rejection must be made explicit.) See MPEP § 2142. “Rejections on obviousness cannot be sustained with mere conclusory statement; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness.” See MPEP § 2142; In re Kahn, 441 F.3d 977, 988, 78 USPQ2d 1329, 1336 (Fed. Cir. 2006); see also KSR Int'l Co., 82 USPQ 2d at 1396. To support a 103(a) rejection, the examiner must demonstrate that a person of ordinary skill in the art would have had reason to attempt to make the claimed device, or carry out the claimed process, and would have had a reasonable expectation of success in doing so. See Noelle v. Lederman, 355 F.3d 1343, 1351–52 (Fed. Cir. 2004); Brown & Williamson Tobacco Co. v. Philip Morris, Inc., 229 F.3d 1120, 1121 (Fed. Cir. 2000); see also KSR Int'l Co., 82 USPQ2d at 1391.

Here, Applicant respectfully disagrees with Examiner that an ethanol or methanol extraction compared with a hot water extraction would inherently result in a composition with the same characteristics or with only slight, unimportant differences. The Examiner stated that it is Applicants' burden to provide evidence illustrating to what extent Applicants' composition differs from Bae et al. In response, Applicant attaches Exhibits 3A-3C. Exhibit 3A is a chromatogram and its three-dimensional plot showing the extraction composition resulting from ethanol extraction; Exhibit 3B is a chromatogram and its three-dimensional plot resulting from

methanol extraction; and Exhibit 3C is a chromatogram and its three-dimensional plot resulting from hot water distraction according to the present disclosure and claimed invention.

Based on this evidence, it is readily apparent that the type or nature of the extraction used to produce extracts from *Nelumbinis Semen* (alcohol versus water) results in very different extraction products. Compare Exhibits 3A and 3B with Exhibit 3C. Exhibits 3A and 3B (ethanol and methanol extractions, respectively) show similar extracted compositions with five distinct peaks and similar three-dimensional plots. However, Exhibit 3C (hot water extraction) shows an extract composition with only two distinct peaks and the absence of peaks 1, 2 and 3 that are present in the ethanol and methanol extractions. Further, a comparison of the three-dimensional plots of Exhibits 3A and 3B with that of Exhibit 3C strongly indicates that the extraction compositions produced from an alcohol or alcohol solution extraction are very different from the extracted composition utilizing hot water extraction.

Thus, contrary to Examiner's assertion, the extraction process claimed in the present application does not inherently produce the same extract compound or composition as the alcohol extractions disclosed in Bae, et al., but rather a very different composition for the treatment of depression. Therefore, Applicants assert that Bae, et al. cannot anticipate, nor render Claims 1, 3-6, 8-9 and 11-12 obvious, and Applicants respectfully request that Examiner withdraw her section 102/103 rejection based on Bae, et al.

C. Rejection Under 35 U.S.C. § 103

The Examiner rejected Claims 1 and 3-12 under 35 U.S.C. § 103 as being unpatentable over Bae et al. in view of Liu (CN Patent No. 1368022 A) and Sohn et al. Claims 7 and 10 have been cancelled, leaving claims 1, 3-6, 8-9 and 11-12 pending in the application.

The Examiner stated Bae et al. teaches a pharmaceutical composition and health food of an extract of Nelumbinis semen for the treatment of depression. The Examiner stated that Bae does not teach water at 80-100 degree Celsius for 1-3 hours and refluxing.

The Examiner stated that Liu teaches lotus seed's embryonic bud is boiled with purified water and features nutritive components; lotus seed is also known as Nelumbinis Semen (see <http://www.tcmbasics.com/materiamedica/semennelumbinis.htm>); and boiling of water in one atmospheric pressure requires the temperature to be 100 degree Celsius.

The Examiner stated that Sohn et al. teaches seeds of N. nucifera extracted with ethanol under reflux for the hours and filtrate was evaporated in vacuo and N. nucifera is also known as Nelumbinis semen or lotus seed (see <http://www.tcmbasics.com/materiamedica/semennelumbinis.htm>).

The Examiner believes it would have been obvious to combine Liu's teaching of a lotus seed's embryonic bud boiled with purified water and features nutritive components with Sohn et al.'s teaching of seeds of N. nucifera extracted with ethanol under reflux for 3 hours and filtrate was evaporated in vacuo, to expect that the process of extracting Nelumbinis semen can be done with water and refluxed for three hours could be used as the types of extracts to treat depression. The Examiner believes that this reasonable expectation of success would motivate one skilled in the art to use water extraction and refluxing for extracting Nelumbinis Semen in the reference composition. Thus, using the process of boiling in water by refluxing for 1-3 hours is considered an obvious modification of the references.

The Examiner noted that the above-listed references do not specifically teach the time span and temperature range disclosed in the current application. However, the Examiner stated

that it would have been customary for one skilled in the art to determine the optimal process in the time span and temperature range to best achieve the desired results.

Applicants assert the combination of Bae, et al., Liu and Sohn cannot render the present invention and specifically Claims 1, 3-6, 8-9 and 11-12 obvious, for the following reasons, all of which have already been articulated above in further detail. First, the alcohol (ethanol and methanol) extractions disclosed in Bae, et al. and Sohn result in a very different Nelumbinis semen extract than that extract produced using the presently disclosed hot water extraction method. Compare again Exhibits 3A and 3B with Exhibit 3C. Thus, alcohol or alcohol solution extractions, and specifically ethanol and methanol extractions, as disclosed in Bae, et al. and Sohn, do not render obvious the Nelumbinis extract claimed in the present application because the extraction method claimed results in a very different extract composition for the treatment of depression that previously disclosed in Bae, et al.

Second, Liu specifically teaches an extraction process for lotus embryonic buds – not embryonic seeds, as used and claimed in the present application. Compare again the lotus seeds used for extraction in Exhibit 2A with embryonic buds shown in Exhibit 2B. The starting products for the extraction are very different, necessarily resulting in different extraction products. See also Lotus Seed (March 2002, <http://www.itmonline.org/arts/lotus.htm>) describing embryonic buds and the very different known medicinal uses of embryonic buds versus lotus seeds (or seed leaves). Liu simply does not teach the hot water extraction method of the present claims for Nelumbinis semen, only for the embryonic buds, which according to Examiner's own reference, has very different properties than the seeds themselves. There is no teaching in Lui that hot water extraction of the lotus seeds would result in a useful extract or composition, as Lui only describes extraction from the embryonic bud.

Therefore, the combination of Bac, et al., Liu and Sohn do not teach, disclose or otherwise make obvious the presently claimed hot water extraction method and technique for extracting the composition shown in Exhibit 3C from Nelumbinis semen, which as shown in the present disclosure, has antidepressive activity and is useful for the treatment for the treatment of depression. Thus, Applicants respectfully request that the Examiner withdraw her section 103 rejection based on the combination of these three references.

CONCLUSION

In view of the foregoing, Applicants believe the claims as amended are in allowable form. In the event that the Examiner finds remaining impediment to a prompt allowance of this application that may be clarified through a telephone interview, or which may be overcome by an Examiner's Amendment, the Examiner is requested to contact the undersigned attorney.

Applicants also submit a \$1,110.00 three-month, large entity extension fee for the following Amendment and Response, thereby extending the deadline to response to the pending Office Action to June 30, 2009. Please credit any over payment or debit any under payment to Deposit Account No. 08-2665.

Respectfully submitted,

HOLME ROBERTS & OWEN LLP

/Christine Meid McAuliffe/
Christine Meid McAuliffe
Registration No. 52,024
Customer No. 23337
Direct Line: (480) 861-9103
Facsimile: (303) 866-0200

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